URETHRAL WARMING SYSTEM

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional application 60/465,128, filed 24 April, 2003, which is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to medical equipment, and particularly to equipment facilitating temperature maintenance of a portion of the body of a patient.

BACKGROUND OF THE INVENTION

Cryo-ablation of the prostate (CAP) is a well-known procedure whereby cold temperatures are applied to diseased tissue of the prostate, typically cancerous tissue, in order to kill the tissue. In applying the cold temperatures, it is necessary to maintain adjacent non-diseased tissue, such as the urethra, at a temperature sufficient to maintain the adjacent tissue vital. Urethral warming systems are known in the art which insert a catheter into the urethra, and which pass warm liquid through the catheter in order to maintain the urethra at a sufficiently high temperature. Such systems typically heat the liquid, and the warmed liquid is forced through the catheter with a pump.

PCT application WO 03/016719 to Adahan, whose disclosure is incorporated herein by reference, describes a vacuum pump which is capable of pumping solid, liquid, or gas, The pump is designed to operate in open-circuit conditions, and to separate out the solids, liquids, and gases as they are introduced into the pump. Sections of the pump are disposable. The pump uses a diaphragm which is oscillated by a motor

European Patent application EP 0801938 to Eshel et al., whose disclosure is incorporated herein by reference, describes liquid thermal treatment apparatus which is adapted to pump warmed liquid through a catheter. The pump used is a peristaltic pump, and certain elements of the apparatus are designed to be disposable.

U.S. Patent application US2002/0116041 to Daoud, whose disclosure is incorporated herein by reference, describes sets of disposable elements which may be used for providing heat transfer fluid to a catheter. The disposable elements include a separate fluid reservoir, filter, heat exchanger member, temperature and pressure

sensor, and fluid supply and return lines.

U.K. Patent application GB2322184 to Moore, whose disclosure is incorporated herein by reference, describes a heating and cooling unit, typically for a baby bottle. The unit comprises a cooling chamber, and a heating cell may be removably inserted into part of the cooling chamber.

U.S. Patent RE37704 to Eshel, whose disclosure is incorporated herein by reference, describes thermal treatment apparatus for thermally treating selected tissues of a subject. The apparatus includes a catheter having an inflatable section for anchoring within a cavity of a patient, and a peristaltic pump for pumping fluid through the catheter.

PCT application WO 02/081354 to Schroder et al., whose disclosure is incorporated herein by reference, describes a system for dispensing a product from a disposable product package. The system includes a pump which may be disposable, and the pump and package may be disposed of when the latter is empty.

SUMMARY OF THE INVENTION

In embodiments of the present invention, apparatus comprising disposable and non-disposable components enables a catheter to be heated. The apparatus comprises a pump unit, a heating unit, and tubing which connects the units and the catheter so as to form a circuit wherein liquid is circulated. The liquid is used to transfer heat to the catheter, which may be inserted into an organ of a patient.

The pump unit comprises a non-disposable pump drive which typically consists of a motor in a housing. The pump unit also comprises a disposable pump which removably couples to the drive, and which is configured to transfer liquid within the pump uni-directionally on operation of the drive. The disposable pump comprises a ventilation unit which allows passage of gas between the section and its surrounding atmosphere, while preventing passage of the liquid from the pump.

The heating unit comprises a non-disposable section and a disposable heated section. The non-disposable section comprises a heating element and a temperature sensor. The disposable section, typically a closed cylindrical container having inlet and outlet orifices configured to transfer the liquid therebetween, is removably mountable in the non-disposable section. When so mounted, the liquid flowing in the disposable section is maintained in good thermal contact with both the heating element and the temperature sensor of the non-disposable section.

The tubing couples the disposable pump, the disposable heated section, and the catheter so that the liquid flows in a closed circuit. The tubing, the disposable pump, the disposable heated section, and the catheter form a sub-assembly of the apparatus, all of the sub-assembly, apart from the catheter, being disposable. Furthermore, the sub-assembly with its contained liquid is completely separable from the other non-disposable portions of the apparatus, facilitating operation and handling of the apparatus in operation room conditions.

There is therefore provided, according to an embodiment of the present invention, apparatus for warming a catheter, including:

a pump unit, consisting of:

a non-disposable pump drive; and

a disposable pump, removably couplable to the pump drive, having an interior volume and an exterior volume between which liquid is transferred uni-directionally on operation of the pump drive, and a ventilation unit configured to allow gas passage between the pump and atmospheric surroundings of the pump while preventing

passage of the liquid therebetween;

a heating unit, consisting of:

a non-disposable section having a heating element and a temperature sensor; and

a disposable heated section, removably couplable to the non-disposable section, having an inlet and an outlet orifice and configured to transfer the liquid therebetween, and to maintain the liquid in good thermal contact with the heating element and the temperature sensor when coupled to the non-disposable section; and

disposable tubing coupling the disposable pump, the disposable heated section, and the catheter, so that the disposable pump, the disposable heated section, and the catheter form a closed circuit for the liquid.

The non-disposable pump drive may include an eccentric coupled to oscillate a connecting rod, and the disposable pump may include a flexible diaphragm which is fixedly attached to the disposable pump and which is configured to removably mate with the connecting rod.

The non-disposable pump drive may include a housing which retains the eccentric and the connecting rod, and which is configured to fixedly retain the disposable pump when the pump is removably coupled to the pump drive.

The interior volume may include a dividing element which constrains the liquid to exit the pump and which is adapted to maintain an air pocket in the pump so as to smooth pulsations of the liquid.

The ventilation unit may include a labyrinth groove which enables the gas passage while preventing the passage of the liquid.

The disposable heated section may include a tube which is configured to direct flow of the liquid therein so as to maintain the liquid in good thermal contact with the temperature sensor.

The tube may be implemented from heat-insulating material, so as to reduce heat transfer between the liquid in the tube and the liquid external to the tube.

The disposable heated section may include fins which are configured to extend a path followed by the liquid between the inlet and the outlet orifice, and to increase the heat transfer between the heating element and the liquid.

There is further provided, according to an embodiment of the present invention, a method for warming a catheter, including:

removably coupling a disposable pump to a non-disposable pump drive, the

disposable pump consisting of an interior volume and an exterior volume between which liquid is transferred uni-directionally on operation of the pump drive, and a ventilation unit configured to allow gas passage between the pump and atmospheric surroundings of the pump while preventing passage of the liquid therebetween;

removably coupling a disposable heated section to a non-disposable section consisting of a heating element and a temperature sensor, the disposable heated section having an inlet and an outlet orifice and configured to transfer the liquid therebetween, and to maintain the liquid in good thermal contact with the heating element and the temperature sensor when coupled to the non-disposable section; and

coupling the disposable pump, the disposable heated section, and the catheter with disposable tubing, so that the disposable pump, the disposable heated section, and the catheter form a closed circuit for the liquid.

The non-disposable pump drive may include an eccentric coupled to oscillate a connecting rod, and the disposable pump may include a flexible diaphragm which is fixedly attached to the disposable pump and which is configured to removably mate with the connecting rod.

The non-disposable pump drive may include a housing which retains the eccentric and the connecting rod, and which is configured to fixedly retain the disposable pump when the pump is removably coupled to the pump drive.

The interior volume may include a dividing element which constrains the liquid to exit the pump and which is adapted to maintain an air pocket in the pump so as to smooth pulsations of the liquid.

The ventilation unit may include a labyrinth groove which enables the gas passage while preventing the passage of the liquid.

The disposable heated section may include a tube which is configured to direct flow of the liquid therein so as to maintain the liquid in good thermal contact with the temperature sensor.

The tube may be implemented from heat-insulating material, so as to reduce heat transfer between the liquid in the tube and the liquid external to the tube.

The disposable heated section may include fins which are configured to extend a path followed by the liquid between the inlet and the outlet orifice, and to increase the heat transfer between the heating element and the liquid.

The present invention will be more fully understood from the following detailed description of the embodiments thereof, taken together with the drawings, a

brief description of which is given below.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic diagram of a urethral warming system, according to an embodiment of the present invention;

Fig. 2 is a schematic diagram of a pump unit of the system of Fig. 1, according to an embodiment of the present invention;

Fig. 3 is a schematic cross-section of a ventilation unit, according to an embodiment of the present invention;

Fig. 4 is a schematic diagram of a heating unit of the system of Fig. 1, according to an embodiment of the present invention;

Fig. 5 is a schematic cross-section of a catheter unit, according to an embodiment of the present invention; and

Fig. 6 is a schematic block diagram of a control unit for the system of Fig. 1, according to an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Reference is now made to Fig. 1, which is a schematic diagram of a urethral warming system 10, according to an embodiment of the present invention. System 10 comprises a pump unit 14 which is formed of a disposable pump 15 mountable on, and removable from, a non-disposable pump drive 17. Pump unit 14 also comprises a ventilation unit 20. System 10 further comprises a heating unit 16, formed of a disposable heated section 19 mountable in, and removable from, a non-disposable heating and temperature sensing section 21. System 10 is a closed circuit liquid pumping system, wherein a liquid 42, typically saline solution although any other suitable liquid may be used, is circulated within the system by pump unit 14, and is maintained at a controlled temperature by heating unit 16. The liquid is circulated through a catheter unit 18. Units 14 and 16 are connected together by disposable tubes 23, 25, and 27. A control unit 12 controls the operation of system 10. Units 12, 14, 16, 18, and 20, as well as a sub-assembly 11 of system 10, are described in more detail below.

In system 10 both the rate of flow of the liquid in the system, and the temperature at which the liquid exits heating unit 16 may be independently set by an operator using control unit 12. System 10 is typically used during a cryo-ablation procedure (CAP) performed on a patient's prostate, to prevent the cold temperatures applied during the CAP from adversely affecting the urethra, and the description below is directed to the use of system 10 during such a procedure. It will be appreciated, however, that system 10 may be used during other procedures where it is required to maintain an organ or part thereof at a controlled temperature.

Fig. 2 is a schematic diagram of pump unit 14, according to an embodiment of the present invention. Pump unit 14 comprises a transparent holding vessel 44, vessel 44 typically being cylindrical, although any other suitable shape may be used. Vessel 44 acts as a reservoir for the liquid that the unit circulates in system 10. In the following description of pump unit 14, it is assumed that an axis of symmetry of vessel 44 is vertical. It will be appreciated however, that, *mutatis mutandis*, vessel 44 may be oriented in directions other than the vertical. Within vessel 44 is an interior divider 46, typically a tube, which divides vessel 44 into an interior volume 40 and an exterior volume 41, the two volumes being isolated from each other. An exterior volume valve 36 controls flow of liquid 42 from exterior volume 41, and an interior volume valve 38 controls flow of liquid to interior volume 40, both valves being set in

a base 45 of vessel 44. Both valves isolate their respective volumes from a common diaphragm volume 43. Both valves are normally closed so that in an inoperative state of system 10 the three volumes 40, 41, and 43 are isolated from each other.

Diaphragm volume 43 is formed from a flexible diaphragm 34 that is mated to base 45. Diaphragm 34 is typically formed from silicone or other synthetic elastic material in the general shape of a cone, and the diaphragm is mated to base 45 so as to ensure that volume 43 is leak-tight. The diaphragm is formed with a protuberance 33 from the lower end of the diaphragm. Holding vessel 44, diaphragm 34, and their associated elements described above comprise disposable pump 15.

Protuberance 33 connects to a connecting rod 32 (Fig. 1), which is driven by an eccentric 30. Eccentric 30 is typically rotated by an electric motor 31 which receives its power from control unit 12. Motor 31, eccentric 30, and rod 32 are housed in a housing 35 which is configured to removably receive disposable pump section 15. When placed in housing 35, vessel 44 is fixedly retained by the housing, and protuberance 33 mates with connecting rod 32. Eccentric 30, motor 31, connecting rod 32, and housing 35 comprise non-disposable pump drive 17.

The movement of connecting rod 32, and the restricted flexure of diaphragm 34, forces the diaphragm to oscillate in a vertical direction, so that volume 43 alternates between a maximum and a minimum volume. The alternation is around a mean volume, formed when system 10 is in its inoperative state. When system 10 operates, valves 36 and 38 are configured so that as diaphragm 34 moves vertically up, i.e., when volume 43 is changing from the maximum to the minimum volume, valve 36 closes and valve 38 opens. This is the case illustrated in Fig. 2, and in this case liquid is forced from diaphragm volume 43 into interior volume 40, and there is no liquid transfer to or from exterior volume 41. When diaphragm 34 moves vertically down, i.e., as volume 43 is changing from the minimum to the maximum volume, valve 36 opens and valve 38 closes. and in this case liquid is forced from exterior volume 41 into diaphragm volume 43, and there is no liquid transfer to or from interior volume 40. Thus, when system 10 is operative, pump unit 14 removes liquid from exterior volume 41, pumps the liquid into interior volume 40, and constrains the liquid flow in system 10 to be uni-directional. Furthermore, the configuration of system 10 ensures that the volume of liquid transferred in one complete rotation of eccentric 30 is substantially constant, and is not dependent on the rate of rotation of the eccentric.

The pump action forces liquid to flow into interior volume 40. The flow rate of the liquid varies as the rate of rotation of eccentric 30, and a sensor 37 measures the rate of rotation. Sensor 37 thus acts as a flow rate sensor, and the value generated by sensor 37 is fed back to control unit 12 for use as an indication of the flow rate of liquid in system 10.

A cylinder 48 within volume 40 guides the liquid so that it is expelled through an upper orifice 59 of interior volume 40. Cylinder 48 acts as a dividing element, within volume 40, that maintains an air pocket 49 in volume 40, the air pocket acting to smooth the pulsating flow of liquid 42 into orifice 59. As described in more detail below, the pump action forces the liquid to flow through the rest of system 10, returning to pump unit 14 via tube 25 coupled to an orifice 61 in exterior volume 41.

At initiation of operation of system 10, pump 15 is mounted in drive 17 and eccentric 30 is activated. The system is most preferably initially sterilized, typically using a sterilizing gas such as ethylene oxide. Ventilation unit 20 is opened, and liquid is introduced via the ventilation unit into exterior volume 41. The operation of eccentric 30 forces liquid from the exterior volume to the interior volume and into the rest of system 10. During initiation, the process of adding liquid to the exterior volume is continued, until the liquid reaches a mark 50 on vessel 44, indicating that no more liquid is to be introduced and that the system has been filled. The position of mark 50 is most preferably determined in an initial calibration of system 10. After filling, ventilation unit 20 is then closed. In its closed state, air may pass through the ventilation unit, but liquid is prevented from passing through.

Fig. 3 is a schematic cross-section of ventilation unit 20, according to an embodiment of the present invention. Unit 20 comprises a generally cylindrical nipple 74 which is fixedly attached to, and which protrudes from, holding vessel 44. Unit 20 also comprises a removable stopper 70, which is configured to mate with nipple 74 so that the nipple and the stopper together provide a labyrinthine groove 72 when the stopper closes the nipple. During operation of system 10 component parts of the system, including liquid 42 and the air in volume 41, change temperature, causing pressure inequalities between the interior of vessel 44 and its atmospheric surroundings. Groove 72 provides a passageway for air, so as to equalize pressures between vessel 44 and the external ambient pressure, while preventing exit of liquid from the vessel to the surroundings. Stopper 70 is preferably retained in proximity to nipple 74 by a flexible connection 76, which enables the stopper to be removed from

and positioned on the nipple.

Fig. 4 is a schematic diagram of heating unit 16, according to an embodiment of the present invention. Disposable heated section 19 of unit 16 comprises an outer vessel 82, typically a cylinder, which is sealed at its top by a heat-insulating stopper 96 through which a heat-insulating inlet tube 84 and an outlet tube 85 penetrate. Tube 84 is formed from a good heat-insulating material such as PVC. A wall 83 of outer vessel 82 is typically constructed from thin material to ensure good thermal transfer across the wall. In an embodiment of the invention, wall 83 comprises a cylinder of 0.5 mm thick aluminum. An outer diameter of wall 83 is configured to be less than an inner diameter of an element 80 (described in more detail below) at ambient temperatures, so that at these temperatures there is a gap of approximately 0.1 mm between wall 83 and element 80.

The base of vessel 82 is sealed by a heat-insulating stopper 92. Stopper 92 is penetrated by a thin metallic cylinder 88, closed at a top 89 of the cylinder so as to form an inverted cup 91. In an embodiment of the invention, cup 91 is implemented from stainless steel having a thickness of 0.05 mm.

Insulating tube 84 is positioned in section 19 so that a lower end of the tube is just above top 89 of cylinder 88. During operation of system 10, liquid 42 is forced down tube 84. The liquid exiting from the tube is flowing at a relatively high speed, and is forced by top 89 to make a radical change in direction of flow. The high speed and change in direction ensure that the liquid comes into good thermal contact with top 89, before flowing in a generally upward path.

Non-disposable section 21 comprises an electric heating element 80, typically cylindrical, which, during operation of the system, heats wall 83 of vessel 82, and the liquid contained by the vessel. Section 21 typically also comprises a safety thermostat 94 which switches power from the heating element in the event that the temperature of the element rises above a pre-set level.

Section 21 also comprises a temperature sensing block 93. Block 93 comprises a good conductor, such as copper, which is configured to be in good contact with cup 91 when section 19 is mounted in section 21. In an embodiment of the invention, block 93 comprises a cylinder having an approximate diameter of 5 mm and an approximate height of 16 mm, and cup 91 has matching dimensions. Block 93 is configured to be in thermal contact with a temperature sensor 90, which is typically embedded in the block.

At initiation of operation of system 10, section 19 is mounted in non-disposable section 21, and power is supplied to heating element 80. The heating causes both the outer diameter of wall 83 and the inner diameter of element 80 to expand. Wall 83 and element 80 are implemented so that the expansion is differential, so that during operation of the system any gap that exists at ambient temperatures disappears, creating very good physical contact, and consequently good thermal contact, between the wall and element 80 during operation of the system. The thermal contact is such as to ensure that there is less than 0.1°C difference between element 80 and the wall.

Also, when section 19 is mounted in section 21, temperature sensor 90 is in good thermal contact with cup 91 and the liquid above the cup, as described above. The good thermal contact is such as to ensure that there is less than 0.1°C difference between a temperature of the sensor and a temperature of the liquid above the cup.

Temperature sensor 90 is thus able to make extremely good measurements of the temperature of the liquid exiting tube 84, before the liquid mixes with the liquid in vessel 82. By implementing tube 84 to be insulating, the temperature measured by sensor 90 corresponds extremely closely to the temperature of the liquid exiting catheter 18, since there is minimal heat transfer across the wall of the tube.

The liquid exiting from tube 84 continues on its upward path within vessel 82 until it exits from unit 16 via outlet tube 85. During its upward flow, the liquid receives heat from element 80. In order to ensure that there is good heat transfer from the element to the liquid, vessel 82 most preferably comprises internal fins 97 which act to both increase the heated area which contacts the liquid, and to lengthen the path followed by the liquid before reaching tube 85. In one embodiment of the present invention, fins 97 are configured to constrain the liquid in vessel 82 to a generally upwardly spiral path. Alternatively or additionally, fins 97 are configured to ensure that the flow of liquid is turbulent during at least part of its path in vessel, so as to improve the heat transfer from element 80.

Fig. 5 is a schematic cross-section of catheter unit 18, according to an embodiment of the present invention. Unit 18 receives liquid 42 from pump unit 14 at an entry orifice 102 via tube 23, and the liquid exits the catheter unit via an exit orifice 104 coupled to tube 25, the orifices being positioned at a proximal end of the catheter. Unit 18 comprises two concentric tubes, an internal tube 106, and an external tube 108, the latter being in contact with the urethra when the catheter is introduced

therein. Liquid entering orifice 102 passes through the interior of tube 106, and returns to orifice 104, from where it is expelled, via the space between the two tubes. External tube 108 is most preferably shaped so as to allow easy entry of the catheter into the urethra, typically by having a rounded bulbous section 110 at the distal end of the catheter.

Fig. 6 is a schematic block diagram of control unit 12, according to an embodiment of the present invention. Unit 12 comprises a regulated power supply 130 which supplies power to heating element 80, thermostat 94, and to motor 31 under control of a central processing unit (CPU) 132, which also acts as a general controller for system 10. Power supply 130 receives its power from the line via a transformer 134 and/or from a battery 136, and is most preferably configured to switch automatically from line power to battery power if the former becomes unavailable. Power supply 130 typically provides power for a cooling fan for unit 12, and for other operating elements of the unit, such as one or more emergency warning lights and/or a buzzer. Power supply 130 also supplies power to CPU 132.

CPU 132 receives control signals from physical parameter sensors of system 10, comprising flow rate sensor 37 and temperature sensor 90. CPU 132 also operates a display 138 and an input control panel 140. The display provides visual information to an operator of system 10 of operating parameters of system 10, such as a temperature measured by sensor 90 and flow rates of fluid in the system. The panel and the display enable an operator to monitor and control the operation of system 10. Control panel 140 enables an operator to input desired values for these parameters to unit 12. CPU 132 controls the power to motor 31 so as to maintain the desired flow rate, and to heating element 80 so as to maintain the desired temperature. CPU 132 performs the controls by issuing control signals to power supply 130.

It will be appreciated that system 10 comprises disposable and non-disposable components. The former include pump 15, heated section 19, and connecting tubes 23, 25, and 27. The disposable components connect to catheter unit 18, to form sub-assembly 11 (Fig. 1) of system 10. Sub-assembly 11 and its contained liquid 42 may be easily removed and/or installed into the remaining non-disposable components of system 10, making for ease of use of system 10 in operation.

It will also be appreciated that the embodiments described above are cited by way of example, and that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present

invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.